UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,527	02/04/2002	Yukihiro Takada	FJN-058C1	8309

21323 7590 03/09/2004

TESTA, HURWITZ & THIBEAULT, LLP
HIGH STREET TOWER
125 HIGH STREET
BOSTON, MA 02110

EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/2

Office Action Summary	Application No.	Applicant(s)	
	10/067,527	TAKADA ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 49-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 49-60 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5-7-02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 49-52 and 57-60 are rejected under 35 U.S.C. 102(b) as being anticipatd by Katzev (US 5002760) in light of Walsh (US5057502).

The claims are drawn to a composition comprising collagen, vitamin D3 and calcium.

The reference teaches a compostion comprising hydrolyzed collagen, vitamin D3, and Aloe vera (see col. 3 and 4). It is well known in the art aloe vera contains calcium oxalate as an active ingredient (see Walsh col. 7, lines 35-40). The reference therefore anticipates the claimed invention. It should be noted that the claims recite various sources and process of degrading collagen. However, since the claims are drawn to a product and since the reference teaches a product comprising the claimed ingredients, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 49-55, 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauk et al. in view of Brenstein et al.

The claims are drawn to a composition comprising collagen, vitamin D3 and calcium.

The reference of Sauk et al. teaches a composition for osseous repair which is prepared by a process comprising mixing a phosphophoryn calcium salt and type I collagen (see col. 3, lines 17-30). The formulation yields a solid composition which is effective to promote new bone growth. The difference between the prior art and the instant application is that the reference does not teach the use of vitamin D3.

However, the reference of Borenstein et al. teach that it is known that certain metabolites of Vitamin D_3 help in increasing the bone strength in hens. Therefore, it would have been obvious to one of ordinary skill in the art to use Vitamin D_3 in conjunction with the composition of Sauk et al. because, one would expect that the addition of Vitamin D_3 to the composition would result in an more effective composition as a bone strengthening agent or a bone growing agent. It is well known, that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426

(1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art.

As for the concentrations claimed, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller , 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Moreover, Sauk et al. does teach that weight ratio of the calcium salt to the type I collagen of about 3.0-0.1:1.

3. Claims 49-55, 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milan et al. (WO 96/05851) in view of Holick et al. (US 4335120) and Kato et al. (US5932259).

Note that the reference applied has been the WO 96/05851, however the English equivalent US 5948766 has been used in the rejection since Applicants did not supply an English translation for the WO reference.

The claims are drawn to a composition comprising collagen, vitamin D3 and calcium.

The reference teach a method of treating osteoporosis comprising administering to a patient in need thereof collagen having a molecular weight of 1 to 40 kda (see col. 2, lines 11-27 and claim 1). The composition can comprise vitamins and calcium salts (see col. 2, lines 48-65 and claim 3 and 6). The dosage used is .5 to 12 g (see claim 8). The reference discloses that hydrolyzed collagen can be obtained by conventional means (see col. 2-3). The difference between the prior art and the instant application is that the reference does not specifically disclose the use of specific calcium salts and vitamin D3.

However, the reference of Kato et al. teach that various calcium salts can be used to strengthen bones. These include calcium carbonate, calcium lactate, egg shell calcium and whey calcium (see col. 1, lines 35-40). The reference also teaches that the agents such as Vitamin D3 can be used to treat osteoporosis (see col. 1, lines 50-53). This teaching is reflected in Holick et al. which teaches that vitamin D3 is effecting in increasing serum calcium has been utilized in treating osteoporosis (see col. 1, lines 14-25). Therefore, given that Milan et al. teach the administration of collagen with calcium salts and vitamins to treat osteoporisis, and Kato et al. and Holick et al. teach independently that calcium carbonate, calcium lactate, egg shell calcium and whey calcium and vitamin D3 are effective in treating osteoporosis, it would have been obvious to combine the collagen, vitamin D3 and a calcium salt. It is well known, that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art.

As for the concentrations claimed, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller , 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach

the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

3/4/04

Anish Gupta
Patent Examiner